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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,579	09/10/2003	Anil Gulati	27611/38545A	4671

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EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,579	GULATI, ANIL	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2003 and 19 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 (in part), 3, 5, 9-25 (in part), drawn to a method of treating Alzheimer's disease or a dementia of vascular origin with a selective endothelin-A antagonist, such as those listed in Appendix A of the specification, classified in class 514, subclasses 378,380, for example.

II. Claims 1 (in part), 6 and 9-25 (in part), drawn to a method of treating Alzheimer's disease or a dementia of vascular origin with a selective endothelin-B antagonist, such as those listed in Appendix C of the specification, classified in class 514, subclass 408, in particular.

III. Claims 1-2 (in part), 4 (in part), 7 and 9-25 (in part), drawn to a method of treating Alzheimer's disease or a dementia of vascular origin with a mixed ET_A/ET_B endothelin antagonist, such as those listed in Appendix B of the specification, classified in class 514, subclass256, for example.

IV. Claims 1-2 (in part), 4 (in part), 8 and 9-25 (in part), drawn to a method of treating Alzheimer's disease or a dementia of vascular origin with an endothelin antagonist having an activity other than those specified above, such as the miscellaneous endothelin antaogonists listed in Appendix D of the specification, classified in class 514, subclass 461, for example.

V. Claims 26-30 (in part), drawn to an article of manufacture or composition having an endothelin antagonist and second therapeutic agent, the

endothelin antagonist being endothelin-A antagonist, such as those listed in Appendix A of the specification, classified in class 514, subclasses 378,380, for example.

VI. Claims 26-30 (in part), drawn to an article of manufacture or composition having an endothelin antagonist and second therapeutic agent, the endothelin antagonist being a selective endothelin-B antagonist, such as those listed in Appendix C of the specification, classified in class 514, subclass 408, for example.

VII. Claims 26-30 (in part), drawn to an article of manufacture or composition having an endothelin antagonist and second therapeutic agent, the endothelin antagonist being a mixed ET_A/ET_B endothelin antagonist, such as those listed in Appendix B of the specification, classified in class 514, subclass 256, for example.

VIII. Claims 26-30 (in part), drawn to an article of manufacture or composition having an endothelin antagonist and second therapeutic agent, the endothelin antagonist having an activity other than those specified above, such as the miscellaneous endothelin antagonists listed in Appendix D of the specification, classified in class 514, subclass 461, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions V-VIII are related to inventions I-IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process as clams could be performed with a materially different product other htan the endothelin antagonist, for example it is known that Alzheimer's may be treated by certain acetylcholinesterase inhibitors such as donepezil.

Because these inventions are distinct for the reasons given above and the search required for Groups I-IV is not required for Groups V-VIII, restriction for examination purposes as indicated is proper. It is noted that while the searches of Groups I-IV may be overlapping with the searches for Groups V-VIII, there is no reason to believe that the searches would be co-extensive. In searching Groups V-VIII, the Examiner will be focusing on the patentability of the product itself, and not the process of using of Groups I-IV. Conversely, in searching Groups I-IV, the Examiner will be focusing on the patentability of the process and not the product itself. Accordingly, a search for both groups would pose an undue burden on the Office.

Inventions I-IV are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the

inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are directed to methods using different types of endothelin antagonists, such as those having endothelin-A or endothelin-B selective antagonists, and thus the inventions having different modes of operation, design and/or function. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. In particular, a search for the claimed methods of treatment including all of the different types of antagonists as claimed, across all applicable classes and subclasses, is deemed to pose an unacceptable search burden on the office.

Inventions V-VIII are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are directed to products having different types of endothelin

antagonists, such as those having endothelin-A or endothelin-B selective antagonists, and thus the inventions having different modes of operation, design and/or function. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. In particular, a search for the claimed methods of treatment including all of the different types of antagonists as claimed, across all applicable classes and subclasses, is deemed to pose an unacceptable search burden on the office.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Upon election of one of Groups I-VIII, Applicants **are further required** to elect from among the following species:

(1) a single disclosed species of endothelin antagonist (e.g. one of compounds 1-35 of Appendix A, or one of compounds 36-45 of Appendix C, etc);

(2) a single disclosed species of second therapeutic agent (e.g. either a cholinesterase inhibitor, a statin, a nonsteroidal anti-inflammatory drug, etc); and

(3) a single disclosed species of disease (e.g. either Alzheimer's or another disclosed dementia of vascular origin.)

Claims 1-30 are generic to species (1), claims 1-13 and 19-30 are generic to species (2), and claims 1-30 are generic to species (3). The species are independent or distinct because they are drawn to distinct conditions and/or compounds that would pose an undue search burden if searched in their entirety. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

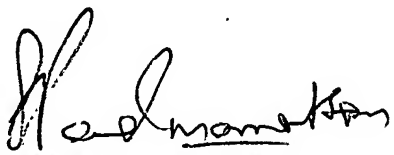
Due to the complicated nature of the restriction, the restriction requirement is being made via written correspondence in lieu of a telephone interview.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC



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